AMENDED IN SENATE APRIL 28, 2005

AMENDED IN SENATE APRIL 11, 2005

SENATE BILL No. 380

Introduced by Senator Alquist

February 17, 2005

An act to add Article 7 (commencing with Section 111657) to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, relating to drugs.

LEGISLATIVE COUNSEL'S DIGEST

SB 380, as amended, Alquist. Drugs: adverse event reporting.

The Sherman Food, Drug and Cosmetics Law provides for the regulation of various subjects relating to the processing, labeling, advertising, and sale of food, drugs, and cosmetics under the administration of the State Department of Health Services. A violation of these provisions is a crime.

This bill would require a licensed health professional and a health facility to report all suspected serious adverse drug events that are spontaneously discovered or observed in medical practice to MedWatch, the drug safety information and adverse event reporting program operated by the federal Food and Drug Administration (FDA), using the FDA 3500 Voluntary form developed by the FDA for MedWatch. The bill would prohibit a licensed health professional or health facility that violates this provision from being subject to the existing penalties and remedies of the Sherman Food, Drug and Cosmetics Law *or any other provision of law*.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) The federal Food and Drug Administration (FDA) operates a voluntary reporting system for adverse drug reactions known as the MedWatch system.

(b) The FDA currently estimates that only 10 percent of the adverse drug reactions or events that occur each year are reported to the FDA.

(c) Given the prevalence of pharmaceuticals and their use for treatment of hundreds of chronic diseases and conditions, and given recent highly publicized instances of commonly used prescription drugs being taken off the market due to safety concerns that were discovered after the drugs were approved for use, the systematic underreporting of adverse drug events represents a serious public health problem.

(d) Requiring licensed health professionals of organizations to report adverse drug events to the FDA would increase the amount of data available to the FDA about adverse drug reactions, thereby enabling the FDA to discern problems with drugs that arise after they are approved and to take action to protect the public health in a more timely manner.

SEC. 2. Article 7 (commencing with Section 111657) is added to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, to read:

Article 7. Adverse Event Reporting

111657. (a) A licensed health professional, including, but not limited to, a physician and surgeon, dentist, or pharmacist, and a health facility, including, but not limited to, a hospital or clinic, shall report all suspected serious adverse drug events that are spontaneously discovered or observed in medical practice to MedWatch, the drug safety information and adverse event reporting program operated by the federal Food and Drug Administration.

(b) For purposes of this section, serious adverse drug events shall include adverse health outcomes involving patients that result in death, life-threatening conditions, hospitalization,

disability, congenital anomaly, or required intervention to prevent permanent impairment or damage.

(c) Any health professional or health facility that is required to report an adverse drug event pursuant to this section shall do so using the FDA 3500 Voluntary form developed by the federal Food and Drug Administration for MedWatch.

111658. A licensed health professional or health facility that violates any provision of this article shall not be subject to the penalties and remedies outlined in Chapter 8 (commencing with Section 111825) *or any other provision of law*.

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